

## **HAND SANITIZER- alcohol gel**

### **Batallure Beauty LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Active Ingredient(s)**

Alcohol 70% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### **Warnings**

For external use only. Flammable. Keep away from heat or flame

### **Do not use**

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

- Put enough product in your palm to cover hands. Rub hands together until dry. Rub hands together until dry.
- Children under 6 years of age when using this product to avoid swallowing.

### **Other information**

- Store between 15-30C (59-86F)

- Avoid freezing and excessive heat above 40C (104F)
- May discolor some fabrics. Harmful to wood finishes and plastics

**Inactive ingredients**

Water (Aqua), Aloe barbadensis leaf extract, Acrylates/ C10-30 alkyl acrylate crosspolymer, Fragrance, Triethanolamine

**Package Label - Principal Display Panel**

50 mL NDC: 76786-073-01



HAND SANITIZER  
Kills 99.99% of common germs\*  
1.7 FL. OZ. / 50 mL

Soothing Gel With Aloe  
\*Kills most common germs,  
based on testing performed using  
ASTM E2315 Standard.

#### Drug Facts

**Active Ingredients**  
Ethyl Alcohol 70% V/V

**Purpose**..... Antiseptic

**Uses:** Hand Sanitizer to  
help reduce bacteria that  
potentially can cause  
disease. For use when soap  
and water are not available.

#### Warnings

For external use only.

Flammable. Keep away  
from heat or flame.

When using this product  
keep out of eyes. ►

Distributed by Botallure Beauty,  
LLC, New York, NY 10022

NOT FOR SALE

#### Drug Facts (continued)

In case of contact  
with eyes, rinse  
eyes thoroughly with  
water. Avoid contact  
with broken skin. Do  
not inhale or ingest.

Stop use and ask  
doctor if irritation or  
rash appears or lasts.  
These may be signs of  
a serious condition.

Keep out of reach of  
children. If swallowed,  
get medical help or  
contact Poison Control  
Center right away.

#### Directions

► Put enough product  
in your palm to cover  
hands. Rub hands  
together until dry.

► Children under 6 ►

HAND SANITIZER

alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76786-073
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARBOMER INTERPOLYMER TYPE A (55000 CPS)</b> (UNII: 59TL3WG5CO)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
<b>1</b>	NDC:76786-073-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/30/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	11/30/2020	05/01/2023

**Labeler -** Batallure Beauty LLC (790417534)

Revised: 11/2021

Batallure Beauty LLC